K000057

MAR - 8 2000

510(k) Summary

Luer Access Universal Vial Adapter

Submitted by:

Mary Ellen Snyder
Senior Manager, Regulatory Affairs
Baxter Healthcare Corporation
I.V. Systems Division
Rt. 120 and Wilson Road
Round Lake, IL 60073

Date Prepared:

February 25, 2000

Proposed Device:

Luer Access Universal Vial Adapter

Predicate Device:

ICU Medical Inc. Clave® Vial Adapter

Proposed Device Description:

The subject of this submission is a Luer Access Universal Vial Adapter, which is intended for use by the pharmacist or nurse in the reconstitution and withdrawal of medications and solutions from drug vials. It allows access to standard sized drug vials (13 mm to 20 mm stoppers) with the male luer adapter on a syringe eliminating the need for conventional metal hypodermic needles and the risk of accidental needle sticks.

The Luer Access Universal Vial Adapter contains a pre-slit luer access septum on top of the adapter. The septum can be accessed by the male luer adapter on a syringe providing direct needleless access to the vial. The luer access septum to be incorporated into the proposed vial adapter is identical to the luer access septum contained in Baxter's Luer Access Injection Site, recently reviewed and cleared by FDA under K984060 on July 26, 1999.

Statement of Intended Use

The Luer Access Universal Vial Adapter is intended for use in the reconstitution and withdrawal of medications and solutions from drug vials. It can be connected to the male

luer adapters of a syringe to allow needleless access to the vial. This device is for use as part of a program to reduce needle-stick injuries and the associated transmission of blood borne pathogens.

Summary of Technological Characteristics of New Device to Predicate Devices

The proposed Luer Access Universal Vial Adapter is similar to the currently marketed ICU Medical Inc. Clave® Vial Adapter, cleared under K934591. Both devices are vial adapters activated by male luer connectors to allow needleless access to a vial. One key difference between the proposed Luer Access Universal Vial Adapter and the Clave® Vial Adapter is the method of operation. The proposed Luer Access Universal Vial Adapter contains a pre-slit septum, which is opened with insertion of a male luer adapter. The septum reseals when the male luer is removed. The Clave® Vial Adapter contains a silicone seal, which is depressed with insertion of the male luer. The silicone seal is penetrated by an internal plastic conduit permitting fluid flow. With disconnection of the luer, the silicone seal springs back above the conduit, resealing it and stopping fluid flow.

There are no new materials involved in the proposed device. All solution contact materials to be used in the proposed device are identical to materials used in legally marketed devices under comparable conditions of use.

Discussion of Nonclinical Tests and Referenced Studies Reported in Published Literature

Performance testing of the proposed Luer Access Universal Vial Adapter has been conducted. A description of the testing along with test results has been provided. All data indicate that the proposed device meets or exceeds all functional requirements and thus support its suitability for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 8 2000

Ms. Mary Ellen Snyder
Senior Manager, Regulatory Affairs
I.V. Systems Division
Baxter Healthcare Corporation
Route 120 & Wilson Road
Round Lake, Illinois 60073-0490

Re: K000657
Trade Name: Luer Access Universal Vial Adapter
Regulatory Class: II
Product Code: FMI
Dated: February 25, 2000
Received: February 28, 2000

Dear Ms. Snyder:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of

the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4690. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number: Not Available K000657

Device Name: Luer Access Universal Vial Adapter

Indication for Use: The proposed Luer Access Universal Vial Adapter is intended for use in the reconstitution and withdrawal of medications and solutions from drug vials. The adapter is accessed by the male luer on a syringe to provide needleless access to the drug vial. This device is for use as part of a program to reduce needle-stick injuries and the associated transmission of blood borne pathogens.

Patricia Cucenda

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K000657